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No. 06-1249

IN THE
Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANE LEVINE,

Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

BRIEF OF AMICI CURIAE VERMONT, ALABAMA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OHIO, OKLAHOMA, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, UTAH, WEST VIRGINIA, VIRGINIA, WASHINGTON, WISCONSIN, AND WYOMING IN SUPPORT OF RESPONDENT

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INTEREST OF THE AMICI CURIAE

The forty-seven amici states, as separate sovereigns in our federal system, have two important interests in the outcome of this case. *First*, the amici are responsible for the enforcement of laws that safeguard public health, safety, and welfare. We therefore have a fundamental interest in preserving the appropriate balance of authority between the states and the federal government. Of significant concern to the amici states are cases involving the amorphous concept of implied preemption. In such cases, Congress has not expressly stated which state-law causes of action—if any—should be eliminated. In our view, courts should only rarely infer that Congress, although silent on the issue, nonetheless intended to displace state law where it is possible to comply with both state and federal law.

Second, this particular case is of crucial importance because the position espoused by Petitioner and the United States would represent an unprecedented elimination of remedies available to consumers injured by drugs. Common law duties play a pivotal role in protecting the health and welfare of the states' citizens. Through the evolution of state common law and by legislative enactments, the states have developed and refined their tort systems to accomplish that end. The amici therefore urge this Court to affirm the decision of the Vermont Supreme Court and reject the sweeping argument advanced by Petitioner and the United States.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case involves the preemptive scope of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), as amended, 21 U.S.C. §§ 301-397. In contrast to the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360k, which expressly preempts "different" or "addition[al]" state requirements with respect to medical devices, the FDCA does not contain an express preemption provision. Petitioner's "implied preemption" argument boils down to the proposition that this Court should construe the FDCA as though it did. In particular, Petitioner argues that Respondent's state-law claim is preempted because it is "impossible" for Petitioner to comply with both state- and federal-law duties (Pet. Br. 29) and because application of state law would "frustrate the public-health objectives underlying the FDCA." Pet. Br. 46. Neither contention has merit.

1. Petitioner's "impossibility" argument cannot be squared with the 70-year history of state tort law operating concurrently with FDA regulation. Injured individuals have long brought state damages actions predicated on faulty drug labels and drug designs. And for the first 60 or so years following the FDCA's enactment, the FDA found it perfectly "possible" for the two regulatory regimes to coexist. Indeed, during that time, the FDA did not even contend that the state actions frustrated achievement of the FDCA's objectives. The FDA's newly-minted assertion, embraced by Petitioner, that state tort law and the FDCA's requirements directly conflict fails the test of history.

2.a. Petitioner's implied frustration preemption argument founders on basic principles of statutory construction and separation of powers. This Court has recognized that the question whether a federal statute displaces state law is an issue of congressional intent. And when frustration preemption is alleged, the key inquiry is whether Congress intended to displace state laws that frustrate full accomplishment of federal objectives.

As a general matter, the answer is that Congress *sometimes* will wish to remove every obstacle in the way of accomplishing federal objectives as quickly and completely as possible. But Congress often has competing objectives, and legislation is often the product of compromise. Congress might conclude, for example, that state tort actions should proceed in order to provide remedies for injured consumers—even if that "frustrates" to some degree the federal goal of uniformity. Similarly, Congress might retain state tort actions as a compromise for having less strict federal standards.

In the end, this paradigmatic policy decision is for Congress, not the courts, to make. Congress knows how to express its intent to displace state laws that it believes stand as obstacles to federal objectives. Literally hundreds of federal statutes contain express preemption provisions. When Congress chooses *not* to include such a provision, that decision should be respected. Adherence to the plain language of federal statutes requires no less. Just as this Court no longer finds private rights of action (except in rare cases), this Court should no longer find frustration preemption (except in rare cases).

That conclusion is buttressed by principles of federalism. Congress's authority under the Commerce

Clause gives it vast opportunities to preempt state law. If the political process is to serve as a genuine check on that power, states must be given notice when their authority is at risk. Implied frustration preemption undermines that check. It also amounts to a presumption *in favor* of preemption because the court is presuming that Congress intended to displace state law. Our federal system should not countenance such a disregard of the states' reserved powers.

For these reasons, courts should infer frustration preemption only when no reasonable policy ground supports the application of state law. When reasonable policy grounds can be asserted both for and against preempting state law, Congress's silence should be construed as a decision *not* to displace state law. And when Congress does not intend to preempt state law on frustration preemption grounds, federal agencies lack the authority to decree that state laws should be preempted on this basis.

b. The FDCA does not express the intent to displace state laws when compliance with state and federal law is possible. Congressional intent to preempt Respondent's state tort action should be found, therefore, only if no reasonable policy grounds support allowing it to proceed. In fact, however, numerous reasonable policy justifications exist: *e.g.*, providing compensation to injured persons, producing new information on the risks of drugs, fear that the FDA is poorly funded and staffed, and the concern that the agency is not nimble enough to respond to information about the dangers posed by products.

Moreover, Congress expressly preempted state law with respect to *other* products regulated by the

FDA; and Congress failed to adopt an express preemption provision in the FDCA even though it was well aware of the long history of state tort actions against drug manufacturers. On top of that, the saving clause in the 1962 Amendments to the FDCA evinced specific intent to limit implied preemption as much as possible. In the end, the FDCA is not one of those rare federal statutes as to which courts should infer congressional intent to displace state laws in the name of frustration preemption.

ARGUMENT

This Court's docket is replete with cases addressing the meaning of express preemption provisions. See, *e.g., Riegel v. Medtronic*, 128 S. Ct. 999 (2008); *Rowe v. N.H. Motor Transport Ass'n*, 128 S. Ct. 989 (2008); *Altria Group, Inc. v. Good*, No. 07-562. The FDCA is striking for its absence of such a provision. In the 70 years since its enactment, Congress has had ample opportunity to preempt state laws applicable to prescription drugs and drug labeling, but has declined to do so. The core issue in this case is what meaning should be attributed to Congress's refusal to express any intent to displace state laws affecting FDA-approved prescription drugs.

Petitioner and its amici essentially argue that the FDCA operates identically to the MDA—that Congress implicitly intended to preempt all state requirements "different from, or in addition to" the federal regulatory regime governing prescription drugs. Their expansive approach to impossibility and obstacle preemption cannot be reconciled with the history of drug regulation or with basic principles of statutory construction, separation of powers, and federalism.

I. It Is Possible To Comply With Both State Common Law And Federal Labeling Regulations Under The FDCA.

Petitioner's impossibility argument is straightforward: the "verdict in this case . . . rested on a state-law duty to change th[e] labeling" of Phenergan (Pet. Br. 33), but "unilaterally alter[ing] the labeling . . . would have been in violation of federal law and subject to enforcement action by FDA." Pet. Br. 30. Respondent's brief fully rebuts the contentions that federal law required Petitioner to distribute Phenergan only with the FDA-approved labeling and that the FDA specifically considered and rejected a label change that would have prohibited or limited intravenous-push injections. Resp. Br. 32-36. Respondent also rebuts Petitioner's more general contention that FDA pre-market approval of a drug label, by itself, is incompatible with a state-law failure-to-warn claim. *Id.* at 36-43. Rather than repeat those arguments, we will limit our submission on this issue to the following point.

Petitioner and other drug manufacturers have had to comply with both federal drug labeling obligations and state common law for 70 years. Far from presenting "irreconcilable" obligations, common law tort suits like the one at issue here have always coexisted with federal labeling requirements. Petitioner's impossibility arguments should therefore be rejected.

To be sure, policy arguments can be made that it might be *unwise* to permit state tort actions challenging labels that were approved by the FDA when the drug was first released. But policy arguments can also be made that a complementary state-federal scheme reasonably balances safety and efficacy in

the pharmaceutical industry while at the same time providing compensation to victims of wrongful injuries. For many years, the FDA itself agreed with the latter arguments. Regardless of who has the better of that policy dispute, one thing this history proves is this: It is *possible* to regulate prescription drugs by having the FDA pre-approve them (and their labels) while also having state juries impose liability when prescription drug labels are found to have provided inadequate warning.

1. This Court has recognized that the states are "vested with the responsibility of protecting the health, safety, and welfare of [their] citizens," and have "great latitude" when carrying out that responsibility. *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 127 S. Ct. 1786, 1795 (2007). "[C]ommon-law damages claims" are "a critical component of the States' traditional ability to protect the health and safety of their citizens." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544 (1992) (Blackmun, J., joined by Kennedy and Souter, J.J., concurring in part and dissenting in part).

Prior to the FDCA's enactment in 1938, a common-law claim for negligence for the manufacture and sale of medicines was widely recognized. See, *e.g.*, *Boyd v. Coca Cola Bottling Works*, 177 S.W. 80, 81 (Tenn. 1915) (holding that drug, food, and beverage manufacturers owe a duty to consumers and that a "tort is committed, a legal right invaded, by practices which prejudice another's health"); *Thomas v. Winchester*, 2 Seld. 397, 1852 WL 4748 (N.Y. 1852) (holding a drug manufacturer liable for a patient's injury). And in the seven decades following the FDCA's passage, the states' traditional common-law

tort systems have continued to compensate injured consumers for injuries caused by prescription drugs.[1]

State tort actions took the federal regulatory regime into account, but in the form of the regulatory compliance defense, which allows juries to consider compliance with federal statutes and regulations when determining a manufacturer's liability. Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims after* Medtronic, 64 TENN. L. REV. 691, 715 (1997); *Restatement (Third) of Torts: Prods. Liab.* § 4 Reporters' Note, cmt. e (1998) (stating that the vast majority of states permit the defense).

If these state tort actions placed prescription drug manufacturers in an impossible bind—forcing them to take actions under state law that federal law prohibited—one would have expected the drug manufacturers to raise the preemption defense at every opportunity. Yet drug companies did not begin to assert preemption as a routine defense until after this Court's ruling in *Cipollone* in 1992. See David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 106 (2005). And when they did

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[1] See, *e.g.*, *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969); *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968); *Phillips v. Roux Labs.*, 145 N.Y.S.2d 449 (N.Y. App. Div. 1955); *Abbott Labs. v. Lapp*, 78 F.2d 170 (7th Cir. 1935); *Valmas Drug Co. v. Smoots*, 269 F. 356 (6th Cir. 1920). See also *Riegel*, 128 S. Ct. at 1017 n.11 (Ginsburg, J., dissenting) (listing 12 other state-law tort actions brought between 1968 and 1975 involving FDA-approved drugs).

assert preemption, the courts almost universally rejected the defense.[2]

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[2] Federal Courts of Appeals: *Abbot v. American Cyanimid Co.*, 844 F.2d 1108, 1112 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988); *Osburn v. Anchor Labs.*, 825 F.2d 908, 911-13 (5th Cir. 1987), *cert. denied*, 485 U.S. 1009 (1988); *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537 (6th Cir.), *cert. denied*, 510 U.S. 914 (1993); *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989); *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986).

Federal District Courts: *In re Vioxx Prods. Liability Litig.*, 501 F. Supp. 2d 776, 788-789 (E.D. La. 2007); *In re Zyprexa Prods. Liability Litig.*, 489 F. Supp. 2d 230, 275-78 (E.D.N.Y. 2007); *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 966-68 (D. Neb. 2006); *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163, 1169 (W.D. Wash. 2006); *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666, 676 (E.D. Ky. 2006); *Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678, 685-88 (E.D. Pa. 2006); *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 731-72 (D. Minn. 2005); *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 882-87 (E.D. Tex. 2005); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1029-44 (S.D. Ill. 2001); *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1091-1100 (C.D. Cal. 2000); *Mazur v. Merck & Co.*, 742 F. Supp. 239, 245-48 (E.D. Pa. 1990); *In re Tetracycline Cases*, 747 F. Supp. 543, 546-50 (W.D. Mo. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1298-1300 (D. Minn. 1988); *Patten v. Lederle Labs.*, 655 F. Supp. 745, 747-50 (D. Utah 1987); *Knudsen v. Connaught Labs.*, 691 F. Supp. 1346, 1347 (M.D. Fla. 1987); *Wack v. Lederle Labs.*, 666 F. Supp. 123, 126-28 (N.D. Ohio 1987); *Foyle v. Lederle Labs.*, 674 F. Supp. 530, 532-34 (E.D.N.C. 1987); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1488-93 (D. Kan. 1987); *Stephens v. G.D. Searle*, 602 F. Supp. 379, 382 (E.D. Mich. 1985).

State Courts: *Carlin v. Superior Court*, 920 P.2d 1347, 1352-53 (Cal. 1996); *Wagner v. Roche Labs.*, 671 N.E.2d 252, 258 (Ohio 1996); *Washington State Physicians Ins. Exchange & Assocs. v. Fisons Corp.*, 858 P.2d 1054, 1068-70 (Wash. 1993); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1185-97 (N.J. 1991), *cert. denied*, 505 U.S. 1219 (1992).

2. If state tort actions placed prescription drug manufacturers in an impossible bind, one would also have expected the federal regulator to step in and try to cure that problem. To the contrary, however, the FDA's longstanding view—modified only this decade—was that drug manufacturers *can* comply with both the FDCA and state tort law.

For example, in 1979 and 1998, the FDA maintained in preambles to drug regulations that state tort law did not interfere with federal regulation. *Prescription Drug Product Labeling; Medication Guide Requirements,* 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998) ("FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations."); *id.* (FDA "regulations establish the minimum standards necessary, but were not intended to preclude the states from imposing additional labeling requirements."); *Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs*, 44 Fed. Reg. 37434, 37437 (June 26, 1979) ("It is not the intent of the FDA to influence the civil tort liability of the manufacturer.").

And as recently as 1997, then-FDA Chief Counsel Margaret Porter opined that Congress "did not intend to preempt state tort remedies for injury to individual consumers." Margaret J. Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 9 (1997). The "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." *Id*. at 11.

The *content* of the FDCA and its pre-approval process did not change between 1979 and 2002, when

the FDA first announced its new pro-preemption position. The "possible" did not suddenly become "impossible." Drug manufacturers were not suddenly barred from revising their labels to deal more effectively with safety concerns; nor did they suddenly become incapable of paying compensation to injured consumers based on pre-approved labels. Rather, what changed was Executive Branch policy concerning the efficacy of allowing state tort actions to proceed against drug companies. Impossibility preemption requires far more than that.

II. The FDCA Does Not Impliedly Preempt State Tort Actions That Purportedly "Frustrate" The Statute's Objectives.

The history described in § I not only undermines Petitioner's contention that compliance with state tort law and the FDCA is impossible; it also undermines Petitioner's separate contention that state tort law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in enacting the FDCA. Pet. Br. 40 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

Petitioner's reliance on obstacle, or frustration, preemption fails for an additional reason: the FDCA expresses no intent whatsoever to preempt any and all state laws that might frustrate "the accomplishment and execution of the full purposes and objectives of Congress." When Congress passes a detailed statute expressing its specific intent on myriad matters, but does not address the displacement of state law, the judicial role is to give effect to the congressional language—including Congress's silence.

Lost in Petitioner's argument is any reference to principles of statutory construction and the infe-

rences that ought to be drawn by comparing the MDA, which contains an express preemption provision, with the FDCA, which does not. The policy-laden decision whether to displace state laws that might stand in tension with federal objectives is for Congress to make. In hundreds of statutes, Congress expressed its intent to preempt state laws that it felt would frustrate the achievement of federal objectives. Congress chose not to include such a provision in the FDCA, a decision that this Court should respect.

A. Principles of statutory construction, separation of powers, and federalism dictate that courts should only rarely displace state law under the doctrine of implied frustration preemption.

Just as this Court no longer reads implied rights of action into statutes except in rare circumstances —regardless of whether such a right of action would further a statute's objectives—so too should this Court no longer find implied frustration preemption except in rare circumstances. In both instances, the decision whether to effectuate Congress's objectives through that particular means is a policy-laden decision that Congress, not the courts, should make.

And in both instances, Congress has shown that it knows how to express its intent. The proper judicial role—particularly given the federalism implications of displacing state law—is to respect the statutory text and Congress's failure to express preemptive intent. So long as Congress would have had reasonable policy grounds *not* to displace state law, courts should not infer frustration preemption.

1. Whether a federal statute preempts state law under the doctrine of implied frustration preemption depends on congressional intent to displace state law.

The Supremacy Clause is the constitutional choice-of-law provision which declares that federal law trumps state law when the two are in direct conflict. But the Clause itself resolves few, if any, preemption disputes. Rather, as the Court has stated time and again, the question in preemption cases "is basically one of congressional intent. Did Congress, in enacting the Federal Statute, intend to exercise its constitutionally delegated authority to set aside the laws of a State?" *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996).

That general statement masks critical nuances, because the precise target of the statutory inquiry varies greatly depending on the type of preemption at issue. In particular, the inquiry differs depending on whether preemption allegedly arises from (1) a statutory provision that expressly preempts state laws, (2) a direct conflict between federal and state law such that it would be impossible to comply with both, or (3) the claim that operation of state law would frustrate achievement of the federal statute's objectives. As will be shown below, when a party claims that a federal statute preempts state law based on implied frustration preemption, the key statutory construction inquiry is whether Congress—notwithstanding its silence on the issue—still in-

tended to displace state laws that frustrate certain purposes or objectives of the federal act.[3]

Express preemption. When preemption is asserted based on an express preemption provision, the statutory construction inquiry concerns the meaning and scope of the provision. To be sure, this inquiry can be complicated by the presence of a saving clause that preserves certain types of state laws from the force of the preemption provision. See, *e.g.*, *Geier v. American Honda Motor Co.*, 529 U.S. 861, 867-74 (2000). But, critically for present purposes, the inquiry in an express preemption case is *not* whether Congress intended to displace state law in the first place. The express preemption provision, by definition, has answered that question.

Impossibility Preemption. Preemption also occurs when "compliance with both federal and state regulations is a physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). The paradigmatic case of "impossibility preemption" occurs when a federal statute says "private entities must do X" and a state law says "private entities may not do X." In that situation, the state law is displaced by direct operation of the Supremacy Clause, which gives the federal statute precedence over a state law that would nullify its operation. The statutory construction inquiry concerns the substantive meaning of the federal statute: what is the meaning of X? The inquiry, again, is *not*

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[3] We do not separately address "field preemption" because the difference between field and non-field preemption is the scope of preempted state law, not the manner by which it is preempted. See 1 Laurence H. Tribe, *American Constitutional Law* 1177 (3d ed. 2000) (noting that field preemption "may fall into any of the . . . categories" of preemption).

whether Congress intended to displace certain state laws.

For example, to borrow from Professor Hart's famous example,[4] if a federal statute declares that "no vehicles shall be permitted in public parks," and a state law provides that "bicycle riding is permitted in parks," the sole statutory construction inquiry would be the meaning of the substantive term "vehicles." If "vehicles" includes bicycles, the state law is preempted by operation of the Supremacy Clause—without any need for Congress to have specifically stated "we intend to displace state laws that directly contradict this statute."

Implied Frustration Preemption. Even where there is no express preemption and it is possible to comply with both federal and state law, this Court has also asked whether the state law nonetheless should be preempted because it would frustrate the full achievement of the federal objectives. See *Hines*, 312 U.S. at 67. In answering that question, the statutory construction inquiry has two distinct targets.

The first inquiry is the same one undertaken in impossibility-preemption cases: discerning the substantive meaning of the federal statute. But in contrast to impossibility-preemption cases, that inquiry does not end the matter. Even if we know exactly what federal standards and rules Congress intended to adopt, there remains the separate question whether Congress intended to displace state laws to better effectuate those standards and rules and the purposes underlying them.

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[4] See H.L.A. Hart, *Positivism and the Separation of Law and Morals*, 71 HARV. L. REV. 593, 607 (1958).

The Supremacy Clause tells us that *if* Congress intended to displace state laws when they frustrate the achievement of certain federal objectives, that federal command controls. The Clause does not, however, answer the predicate question whether Congress so intended. That issue is a matter of statutory construction.

Critically, it is simply not the case that Congress always, or even usually, intends to preempt any and all state laws that might somehow "frustrate" achievement of one of its objectives. For example, one goal of Congress might be to "foster[] uniformity in . . . regulations," but that objective may not be "unyielding." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 70 (2002). A state tort action that frustrates the goal of uniformity might advance legislators' expectation that injured consumers have access to remedies. *Id.* at 64 (state tort actions, "unlike most administrative and legislative regulations[,] necessarily perform an important remedial role in compensating accident victims").

Similarly, Congress might conclude that state tort liability provides a necessary supplement to a regulatory regime by "spurring change in regulatory or corporate procedures, as well as extending knowledge about drug risks by adding to the evidence available for evaluation by physicians, patients, and regulators." Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 310 (2007); see also *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) ("tort suits can serve as a catalyst" to improve industry and federal regulatory practices).

Or a statute might reflect a compromise in which legislators who wanted stricter federal standards

settled for laxer standards in exchange for *not* displacing state tort actions. See *Landgraf v. USI Film Prods.*, 511 U.S. 244, 286 (1994) ("Statutes are seldom crafted to pursue a single goal, and compromises necessary to their enactment may require adopting means other than those that would most effectively pursue the main goal.").

As Professor Nelson has explained, even if we "suppose that all members of Congress can agree on the 'full purposes and objectives' behind a particular federal statute[,] [t]here still is no reason to assume that they would want to displace whatever state law makes achieving those purposes more difficult." Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 280 (2000). For as this Court "has acknowledged outside the realm of preemption, 'no legislation pursues its purposes at all costs,' and 'it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute's primary objective must be the law.'" *Id.* (quoting *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987)).

Amici Chamber of Commerce and Product Liability Advisory Council (PLAC) are therefore wrong when they assert that congressional intent to displace state law is irrelevant to the implied frustration preemption inquiry. See Chamber Br. 23-26; PLAC Br. 16 ("Conflict preemption does not depend on an inference of congressional intent."). That is true only when compliance with both state and federal law is impossible. At that point, the Supremacy Clause kicks in and nullifies state law. Short of impossibility, the displacement of state law is not *necessary*; rather, it is a policy judgment. And Congress, not the courts, is the appropriate institution to make that policy judgment.

The Chamber acknowledges that the issue "is a matter of judgment" that requires courts to discern congressional "purpose" and whether the tension between state law and that purpose "is sufficient." Chamber Br. 24, 25. But, argues the Chamber, "[t]he law is filled with broad concepts— reasonableness, probable cause, excusable neglect, good cause, ordinary care—that call for the judicial exercise of judgment." *Id.* at 25. That is no doubt true, but the courts' role in interpreting statutes is far different from their role adjudicating tort and contract actions. When construing a statute, a court's "role is to interpret the language of the statute enacted by Congress," not to "satisfy policy preferences of the" parties, which "are battles that should be fought among the political branches and the industry." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 461-62 (2002).

In short, sometimes Congress will decide as a policy matter that achievement of certain statutory ends warrants casting aside all state laws that might hinder attainment of those ends. Sometimes, however, Congress will decide as a policy matter (or as a compromise) that competing interests served by state law—for example, providing remedies to injured persons—outweigh the costs imposed on a particular federal objective. When assessing whether a federal statute preempts a state law based on implied frustration preemption, a court must decide how Congress resolved that policy question.

As we explain below, ordinary tools of statutory construction dictate that when Congress has not spoken to the issue of preemption, courts should only rarely conclude that Congress nonetheless intended

to displace state laws that purportedly frustrate achievement of one of the federal statutory goals.[5]

2. Standard tools of statutory construction militate against finding implied frustration preemption.

a. Statutory interpretation begins, of course, with the text. "When the statutory language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." *Arlington Cent. School Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (internal quotation marks omitted). The terms of statutes—such as the FDCA—that do not contain a preemption provision are clear: they express no apparent intent to displace state law.

When Congress wishes to displace state law in order to achieve federal objectives more efficiently, it knows how to do so. By one count, Congress has enacted 355 statutes that contain express preemption provisions. See James T. O'Reilly, *Federal Preemption of State & Local Law* § 1.2, at 2 (2006). Congress's decision *not* to express any intent to displace state law should therefore be given great weight.

Indeed, this Court routinely defers to congressional silence where Congress has expressly spoken on a given issue in other statutes. See, *e.g.*, *Kimbrough v. United States*, 128 S. Ct. 558, 571 (2007) ("Drawing

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[5] We recognize that the Court stated in *Geier* that it did not wish to "drive[] a legal wedge" between impossibility and implied frustration preemption. 529 U.S. at 873. But *Geier* cannot reasonably be construed as suggesting that there are no differences whatsoever between how the two types of preemption are analyzed.

meaning from silence is particularly inappropriate here, for Congress has shown that it knows how to direct sentencing practices in express terms."); *Whitfield v. United States*, 543 U.S. 209, 216-217 (2005) ("Congress has included an express overt-act requirement in at least 22 other current conspiracy statutes, clearly demonstrating that it knows how to impose such a requirement when it wishes to do so. . . . Where Congress has chosen *not* to do so, we will not override that choice. . . ."); *Dole Food Co. v. Patrickson*, 538 U.S. 468, 476 (2003) ("Where Congress intends to refer to ownership in other than the formal sense, it knows how to do so. Various federal statutes refer to 'direct and indirect ownership.' The absence of this language in 28 U.S.C. § 1603(b) instructs us that Congress did not intend to disregard structural ownership rules." (internal citations omitted)); *Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc.,* 484 U.S. 49, 57 (1987) ("Congress has demonstrated in . . . other statutory provisions that it knows how to avoid this prospective implication by using language that explicitly targets wholly past violations."); see also *Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1582 (2007) (Stevens, J., dissenting) ("To begin with, Congress knows how to authorize executive agencies to preempt state laws. It has not done so here." (internal footnote omitted)).

When the Court declines to read unexpressed preemptive intent into federal statutes, it acts in a manner consistent with well-established statutory canons. One "cardinal principle of statutory construction" is that "a statute ought . . . to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *Duncan v. Walker,* 533 U.S. 167, 174 (2001) (internal quotation marks omitted). Although the

anti-surplusage canon is typically employed to understand the meaning of one congressional enactment, its logic applies to construing separate statutes. Inferring frustration preemption makes surplusage out of many of Congress's express preemption provisions. An obvious example is the MDA's preemption provision, which serves no purpose if Petitioner's frustration preemption theory is correct.

Second, "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal quotation marks and citations omitted). Although, as with the anti-surplusage canon, this principle speaks to the "inclusion or exclusion" within a statute, its logic also applies when comparing statutes. When Congress includes preemption provisions in more than 350 statutes and does not include such provisions in other statutes, Congress should be "presumed" to have "act[ed] intentionally and purposefully."

A further reason not to infer congressional intent to displace state laws in the face of congressional silence is the difficulty of discerning Congress's purposes. Frustration preemption is premised on state laws being an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67. What if, however, the federal statute was the product of a compromise or contains multiple "purposes and objectives" that are in some tension with each other? See *Fitzgerald v. Racing Ass'n of Cent. Iowa*, 539 U.S. 103, 108 (2003) (noting that the state law under review, "like most

laws, might predominantly serve one general objective . . . while containing subsidiary provisions that seek to achieve other desirable (perhaps even contrary) ends as well, thereby producing a law that balances objectives but still serves the general objective when seen as a whole"). A state law might frustrate accomplishment of the "general objective," but further "achieve[ment]" of "other desirable . . . ends." *Id.* Only the statutory text can resolve whether Congress intended to preempt state law in such circumstances.

Given these considerations, it is not surprising that a majority of the members of the Court has expressed concern with the concept of implied frustration preemption. See *Bates,* 544 U.S. at 459 (Thomas, J., joined by Scalia, J., concurring in the judgment in part and dissenting in part) (approving "th[e] Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"); *Geier,* 529 U.S. at 907 (Stevens, J., joined by Souter, Thomas, and Ginsburg, JJ., dissenting) (discussing the importance of "prevent[ing] federal judges from running amok with our potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes"); *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part, concurring in judgment) ("A freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law.").

b. This approach to implied frustration preemption—focusing on text, not on furthering perceived congressional purpose—parallels the Court's ap-

proach to implied rights of action. Before 1975, the Court "placed considerable emphasis upon the desirability of implying private rights of action in order to provide remedies thought to effectuate the purposes of a given statute." *Transamerica Mortgage Advisors, Inc. v. Lewis,* 444 U.S. 11, 15 (1979). As a result, the Court's "probe of the congressional mind . . . never focused squarely on private rights of action, as distinct from the substantive objects of the legislation." *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1103 (1991). This changed in a series of cases beginning with *Cort v. Ash*, 422 U.S. 66 (1975).

The key inquiry now is whether Congress specifically intended to create a private right of action. See *Virginia Bankshares*, 501 U.S. at 1104; *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 812 n.9 (1986) (collecting cases). And "unless this congressional intent can be inferred from the language of the statute, the statutory structure, or some other source, the essential predicate for implication of a private remedy simply does not exist." *Northwest Airlines, Inc. v. Transport Workers*, 451 U.S. 77, 94 (1981). Although not dispositive, "congressional silence . . . is thus a serious obstacle" to finding private rights of action. *Virginia Bankshares*, 501 U.S. at 1104.

The Court changed its approach to implying private rights of action for many reasons, one of which has particular resonance here. The Court observed in *Virginia Bankshares* that, while the text and legislative history of § 14(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78n(a), "carry the clear message that Congress meant to protect investors from misinformation . . ., it is just as true that Congress was reticent with indications of how far this protec-

tion might depend on self-help by private action." 501 U.S. at 1103-04. Congress does not pursue its objectives at all costs and through all means. It is therefore up to Congress, not the courts, to specify the means—whether they be private rights of action or the displacement of state law.

3. Principles of federalism further militate against finding implied frustration preemption.

a. This Court has frequently recounted the reasons why the Framers adopted a federal structure of government and the advantages that accrue from it. Allowing States to exercise continued power ensures that government is "more sensitive to the diverse needs of a heterogeneous society"; "increases opportunity for citizen involvement in democratic processes"; "allows for more innovation and experimentation in government"; and "makes government more responsive by putting the States in competition for a mobile citizenry." *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

When state laws are preempted, none of those interests is served. This concern may not have been paramount earlier in the Republic, when Congress's powers were viewed as narrower, and federal law was "generally interstitial in its nature." Henry M. Hart, Jr. and Herbert Wechsler, *The Federal Courts and the Federal System* 470 (2d ed. 1973). Now, however, Congress's authority under the Commerce Clause is vast, see *Gonzales v. Raich*, 545 U.S. 1, 17 (2005) (confirming Congress's "power to regulate purely local activities" that substantially affect interstate commerce), and the opportunities to preempt state law are correspondingly broad.

Recognizing this concern, the Court has adopted a series of clear statement rules applicable when Congress encroaches upon state powers. See, *e.g.*, *Gregory*, 501 U.S. at 460-61 (adopting "plain statement" rule when Congress "would upset the usual constitutional balance of federal and state powers"); *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985) (requiring plain statement before construing statute to abrogate states' sovereign immunity); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (stating "assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress").

These rules serve a crucial structural function: "inasmuch as th[e] Court in *Garcia* [*v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528 (1985)] has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise." *Gregory*, 501 U.S. at 464. States cannot protect their interests through the political process if Congress has not signaled that it intends to trench on the states' domain.

The doctrine of broad implied frustration preemption is irreconcilable with these principles. Indeed, the doctrine amounts to a presumption *in favor* of preemption because the court is presuming that Congress, although silent on the issue, would have wanted state law displaced. This not only conflicts with basic canons of statutory construction and the judiciary's institutional role, see §§ II(A)(1) and (2), *supra*, but undermines the protections the political process is designed to afford the states. As then-

Justice Stone once wrote, "[a]t a time when the exercise of the federal power is being rapidly expanded through Congressional action, it is difficult to overstate the importance of safeguarding against such diminution of state power by vague inferences as to what Congress might have intended if it had considered the matter or by reference to our own conceptions of a policy which Congress has not expressed and which is not plainly to be inferred from the legislation which it has enacted." *Hines*, 312 U.S. at 75 (Stone, J., dissenting).

b. As noted above, the longstanding presumption against preemption is one tool for protecting the states' status as "independent sovereigns in our federal system." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) quoted in *Bates*, 544 U.S. at 449. "This assumption provides assurances that the federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (internal quotation and citation omitted).

The arguments set forth in §§ II(A)(1) and (2), *supra*, are independent from, but complementary to, the presumption against preemption. Principles of statutory construction and the proper institutional roles of Congress and the courts dictate that implied frustration preemption should only rarely be found; federalism principles reinforce that conclusion. The federalism-based presumption against preemption, and its concomitant clear-statement rule, leads to the same result.

The Chamber and PLAC devote most of their energies to arguing that the presumption against preemption does not apply to cases involving implied preemption. Their argument fails on its own terms,

as others have explained.[6] But more fundamentally, that argument is beside the point because it fails to reckon with the statutory construction, separation of powers, and federalism concerns addressed herein. At the very least, in the implied frustration preemption context, the presumption against preemption is a tool for effectuating the conclusion that implied frustration preemption should rarely be found.[7]

4. Inferring frustration preemption is only proper when no reasonable policy ground supports applying state law.

We are not suggesting that frustration preemption can *never* be found. A state law might so undermine the achievement of manifest federal objectives that no reasonable legislator would have voted for a bill knowing that such a state law would operate. Conversely, however, a state law should not be displaced where a reasonable policy ground supports its application.

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[6] See generally Brief of Public Justice, P.C., as *Amicus Curiae*, *Warner-Lambert Co. v. Kent*, No. 06-1498, at 5-29 (demonstrating that this Court has long and often applied the presumption in implied-preemption cases and explaining the purposes of the presumption in such cases).

[7] The Chamber (Br. 14, 18) and PLAC (Br. 14-15, 17) both rely heavily on Professor Nelson's conclusion that the presumption against preemption lacks a historical basis, but they fail to mention his conclusions that "the modern doctrine of 'obstacle' preemption has no place as a doctrine of constitutional law," that "obstacle preemption cannot be defended as a general doctrine of statutory interpretation," and that the presumption against preemption "makes some sense within the framework that the Supreme Court has developed for preemption cases" by "offset[ting] its . . . expansive formulations of 'implied' preemption." 86 VA. L. REV. at 266, 290, 304.

This "reasonable policy ground" rule implements the statutory construction, separation-of-powers, and federalism concerns discussed above. The choice whether to preempt state law is for Congress to make. It knows how to express its intent to displace state laws when that is its intent; and the interests served by our federal system are undermined when state laws are implicitly preempted by federal acts. Taken together, the general rule must be that courts should not "expand federal statutes beyond their terms through doctrines of implied pre-emption." *Bates*, 544 U.S. at 459 (Thomas, J., concurring in the judgment in part and dissenting in part).

Congress, not the courts, is charged with "the difficult policy choice[]" whether to displace state laws that stand in tension with certain federal objectives. *Ewing v. California*, 538 U.S. 11, 28 (2003). If reasonable policy arguments can be asserted both for and against displacement of state law, congressional silence is properly construed as a decision *not* to displace state law.

5. Federal agencies lack the authority to deem state laws preempted under the doctrine of implied frustration preemption.

When the ordinary tools of statutory construction reveal that Congress did not intend to displace state law, that ought to end the implied frustration preemption inquiry. As occurred here, however, federal agencies sometimes independently assert their view that state laws that frustrate achievement of federal objectives are preempted. See 71 Fed. Reg. 3922, 3934-35 (2006). The amicus brief by Professor Merrill on behalf of the Center for State Enforcement of Antitrust and Consumer Protection Laws compre-

hensively addresses the deference, if any, an agency should receive when it opines that state law is preempted. For present purposes, an additional observation is in order.

In *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001), this Court held that "it is most certainly incorrect to say that language in a regulation can conjure up a private cause of action that has not been authorized by Congress. Agencies may play the sorcerer's apprentice but not the sorcerer himself." That holding fully applies to agency efforts to "conjure up" implied frustration preemption. It is one thing for an agency to exercise statutorily-delegated authority by promulgating a substantive regulation, and for that substantive regulation to preempt state laws that directly contradict it. See *Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141 (1982) (agency rule permitting federal savings and loan associations to use "due-on-sale" clauses in mortgage contracts preempts California's prohibition of such clauses). But it is quite another thing for an agency to declare that, even though Congress did not intend to displace state laws that could frustrate full achievement of the federal objectives, the agency has authority to declare that state laws will be preempted on that ground.

When an agency engages in the former action, it is playing the sorcerer's apprentice; when it engages in the latter action, it is improperly playing the sorcerer himself. Put another way, "if Congress does not intend [implied frustration] preemption, Congress should be held not to intend agency [implied frustration] preemption." Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 NW. U. L. REV. 695, 707 (2008) ("*Agency Preemption*").

For precisely this reason, an agency cannot manufacture preemption by declaring that a standard it has adopted is both a "floor" and a "ceiling." See, *e.g.*, 71 Fed. Reg. at 3935 (FDA's assertion that its labeling requirements "establish both a 'floor' and a 'ceiling'"). Such assertions are invariably followed by the contention that any state measures that impose stricter standards or additional requirements are preempted because they directly conflict with the federal ceiling. See, *e.g.*, U.S. Br. 19. The problem with this approach is that the agency's declaration that its standard is a ceiling is nothing more than a declaration that it is invoking implied frustration preemption.

As Professor Mendelson observes, it is commonplace for agencies to be charged with accomplishing primary goals (*e.g.*, providing a safe workplace, ensuring that drinking water is healthy, making automobiles safer) as well as "countervailing or moderating goals" (*e.g.*, reducing costs to employers, increasing flexibility for manufacturers). *Agency Preemption*, at 709-14. If agencies are allowed to declare their standards to be both floors (to achieve the primary goals) and ceilings (to achieve the countervailing secondary goals), "federal agencies would have the power to preempt nearly any state law operating in the same arena as the federal law." *Id.* at 714. For "[a]n agency can nearly always identify some statutory goal—perhaps opposed to or in tension with the statute's primary goal—with which the state law will conflict." *Id.* at 713; see also *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 646 (1990) ("[T]here are numerous federal statutes that could be said to embody countless policies.").

If Congress wishes to grant agencies that massive power, it generally may do so. But where Congress does not express the intent to preempt state laws merely because those laws might frustrate full accomplishment of the federal objective, Congress also did not intend to grant federal agencies the authority to do precisely that under the guise of setting floors and ceilings.

B. In enacting the FDCA, Congress did not express an intent to displace state laws that purportedly frustrate achievement of the statute's objectives.

Because the FDCA lacks an express preemption provision, principles of statutory construction, separation of powers, and federalism weigh heavily against inferring congressional intent to displace state laws with which it is possible to comply. This is not the rare case where frustration preemption should be implied.

Reasonable policy grounds support allowing state tort actions such as Respondent's to proceed; Congress expressly preempted state law with respect to *other* products regulated by the FDA; Congress failed to take express preemptive action notwithstanding the long history of state tort actions against drug manufacturers; and Congress adopted a saving clause in 1962 to limit the FDCA's preemptive scope. All told, Congress's decision not to include an express preemption provision in the FDCA is properly viewed as a decision *not* to displace state tort actions.

1. As explained earlier, if reasonable policy arguments can be asserted both for and against displacement of state law, congressional silence is prop-

erly construed as a decision not to displace state law. That is the situation here.

In *Riegel*, the Court "speculate[d]" that the reason Congress probably wanted the MDA's preemption provision to cover state tort actions was "solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." 128 S. Ct. at 1009. That is a plausible policy justification for preempting state tort actions against prescription drug manufacturers as well. But there are plenty of plausible policy justifications for *not* preempting such actions.

Specifically, Congress may have wanted injured consumers to retain the right to bring tort actions against prescription drug manufacturers:

- to avoid the "harsh implications of foreclosing all judicial recourse for consumers injured" by defective drugs or inadequate drug labels. See Porter, 52 FOOD & DRUG L.J. at 9; *Sprietsma*, 537 U.S. at 64 (state tort actions, "unlike most administrative and legislative regulations[,] necessarily perform an important remedial role in compensating accident victims").

- because tort suits "aid in the exposure of new dangers," which leads manufacturers and federal regulators to address the problems. *Bates*, 544 U.S. at 451.

- based on the concern that "pre-approval testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies." David Kessler & David C. Vladeck, *A Critical Examina-*

tion of the FDA's Efforts to Preempt Failure-to-Warn Claims, 96 GEO. L.J. 461, 471 (2008).

- based on the concern that the FDA is overworked and underfunded, and therefore cannot ensure that defective and dangerous devices will not reach consumers. See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 498-500 (1997).
- based on the concern that the post-approval monitoring system is not up to the task of protecting consumers from drugs whose defects become apparent only after initial FDA approval. See Kessler & Vladeck, 96 GEO. L.J. at 483-95.

In the end, it is for Congress to decide whether the policy considerations noted in *Riegel* outweigh the policy considerations outlined above. Congress's decision not to include an express preemption provision in the FDCA reflects a decision to accept the policy arguments against displacing state tort actions against prescription drug manufacturers.

2. That conclusion is reinforced by Congress's treatment of state law as applied to other products regulated by the FDA. Congress has expressly preempted certain state actions based on injuries arising from medical devices, 21 U.S.C. § 360k(a), and vaccines, 42 U.S.C. §§ 300aa-22(b)(1) and (e); and has preempted state positive-law requirements with respect to over-the-counter drugs, 21 U.S.C. § 379r(a). Congress's decision not to enact a provision expressly preempting state actions against prescription drug companies is therefore telling.

We noted earlier the principle that "where Congress includes particular language in one section of a

statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion." *Russello*, 464 U.S. at 23 (internal quotation marks and citations omitted). That principle applies here.

"The long history of tort litigation against manufacturers" of prescription drugs, and Congress's refusal to amend the FDCA in response, "adds force to" the conclusion that Congress did not intend to preempt such litigation. *Bates*, 544 U.S. at 449. As discussed in § I, *supra*, state tort law has operated concurrently with FDA regulation from the beginning. When Congress crafted the preemption provision in the MDA, it was surely aware that "[j]udgments against manufacturers of various FDA-approved products were by no means rare." Leflar & Adler, 64 TENN. L. REV. at 704. Nevertheless, Congress opted to preempt only state requirements with respect to medical devices—*not* state requirements with respect to drugs. As this Court observed in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there is between them." 489 U.S. 141, 166-67 (1989) (internal quotation omitted).

3. Finally, the saving clause adopted as part of the 1962 Amendments to the FDCA confirms that the statute does not impliedly preempt state law. The provision states:

> Nothing in the amendments made by this Act to the Federal Food, Drug, and

> Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of state law.

Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).

As a threshold matter, it bears emphasis that not even Petitioner suggests that Congress adopted § 202 in order to *expand* the statute's preemptive scope. Rather, Congress sought to ensure that the courts would not "construe[]" the statute in an overly preemptive manner. *Id.* The general rule against implied frustration preemption should therefore apply with full force to the FDCA.

Turning to the provision's precise meaning, § 202 is properly read as a declaration that state laws are preempted by the FDCA only under the doctrine of impossibility preemption. Section 202's language was borrowed from a pending piece of legislation, H.R. 3, Establishing Rules of Interpretation for Federal Courts Involving the Doctrine of Federal Preemption. See H.R. Rep. No. 1820, 87th Cong., 2d Sess. (June 13, 1962) ("H.R. 3 Report"). Earlier versions of H.R. 3 had been introduced in the 1950s; the amended version reported favorably out of the House Judiciary Committee in June 1962 provided, in pertinent part, as follows:

> [1] No Act of Congress shall be construed as indicating an intent on the part of Congress to occupy the field in which such Act operates, to the exclusion of all State laws on the same subject matter, unless such

> Act contains an express provision to that effect. [2] No provision of an Act of Congress shall be construed as invalidating a provision of State law which would be valid in the absence of such Act, except to the extent that there is a direct and positive conflict between such provisions so that the two cannot be reconciled or consistently stand together.

H.R. 3 Report, at 13. The first sentence explicitly prohibits courts from invoking implied field preemption. The second sentence goes further, and prohibits courts from impliedly preempting state law unless "there is a direct and positive conflict between" federal and state law.

The House debates with respect to the 1962 FDCA Amendments specifically discussed "H.R. 3 clauses,"[8] and it is plain that the FDCA saving clause (proposed in September 1962) adapted the second sentence of H.R. 3. This background teaches two critical lessons about the meaning of § 202 of the FDCA Amendments.

First, Congress knew how to bar field preemption, and only field preemption, if that was its intent. This is what the first sentence of H.R. 3 did. Second, and relatedly, Congress did not want the FDCA saving clause to address only field preemption. If that was Congress's intent, it would have borrowed the *first* sentence of H.R. 3, not the *second* sentence.

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[8] See 108 Cong. Rec. 21,045, 21,046 (Sept. 27, 1962) (statement of Rep. Smith) ("[w]e have all heard of H.R. 3"); *id.* at 21,047 (statement of Rep. Meader) (noting that recently the judiciary committee has been "careful to insert . . . a little H.R. 3 declaration").

The framers of the 1962 Amendments to the FDCA were concerned that "by giving additional authority to the Food and Drug Administration, we may be striking down existing State laws and interfering with existing State machinery in this field." 108 Cong. Rec. 21,045, 21,047 (Sept. 27, 1962) (statement of Rep. Meader).[9] Although the Amendments did not *expressly* preempt state laws, the concern was that they might be found to *impliedly* do so. The framers therefore inserted the saving clause—borrowed from H.R. 3—to make clear that only if state and federal law truly could not stand together would state law be preempted.

All told, the saving clause represents a powerful indication that Congress disfavored implied preemption altogether. At the very least, it further supports the conclusion that the FDCA is not the rare statute in which Congress intended to preempt state law under the doctrine of implied frustration preemption.

CONCLUSION

The judgment of the Vermont Supreme Court should be affirmed.

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[9] See also 108 Cong. Rec. at 21,056 (statement of Rep. Scheneck) ("Many very helpful State laws are in effect; many such laws in some instances are even stronger than Federal laws for the protection of human health in the public interest. We here in the Congress should take no action to interfere with these strong and effective laws already approved by State legislatures and doing very effective work in this important effort to protect and improve human health."); *id.* at 21,083 (statement of Rep. Harris) (saving clause was consistent with his "categorical statement that this legislation did not preempt any State laws and was not so intended").

Respectfully submitted,

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